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(54) Nozzle member provided with sealing membrane.

(57) A nozzle member (20) is mounted to a medical solution container for providing an inlet port of an additional medical solution introduced into the container by means of a needle. The nozzle member (20) comprises a tubular body (21) and a synthetic resin sealing membrane (25) mounted within the tubular body (21). Projections (27a and 27b) are formed on both surfaces in the central portion of the sealing membrane (25) so as to prevent the sealing membrane (25) from being strained or cracked in the step of thermally sterilizing the medical solution container.

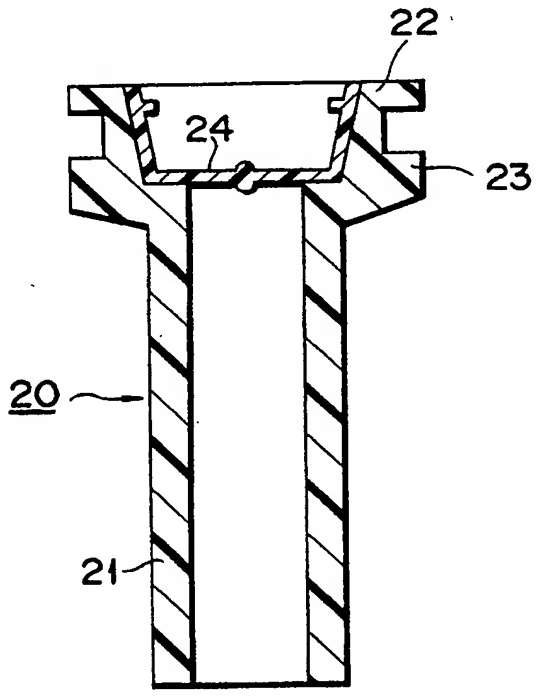

FIG. 4

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Nozzle member provided with sealing membrane

The present invention relates to a nozzle member provided with a sealing membrane. The nozzle member is used as an injection port of, for example, a peritoneal dialysing fluid bag, a parenteral solution bag or a blood bag.

The nozzle member of the present invention is used in, for example, a peritoneal dialysing fluid bag, which is shown in Fig. 1. Fig. 2 is a cross sectional view along line II-II shown in Fig. 1. As seen from the drawings, the bag comprises a bag body 10 prepared by heat-sealing the edge portion 12 of a soft polyvinyl chloride (PVC) sheet 11 manufactured by means of inflation molding. A dialysing fluid is housed in the inner space 13 of the bag body. A sealing tubular body 14 formed of PVC is mounted at the lower end portion of the bag body 10 so as to provide an outlet port. The tubular body 14 extending into the inner space 13 is fixed by fusion to the sheet 11. A conduit 16 is connected to the outer open end of the tubular body 14. The other end of the tubular body 14 positioned within the inner space 13 is sealed. Also, a constricted portion 15 is formed in that portion of the tubular body 14 which is positioned within the inner space 13 and close to the bottom of the bag body 10.

Further, a nozzle member 17 for injection of a medical solution into the bag is formed at the lower end portion of the bag body 10. The nozzle member 17 comprises a tubular body 17a, which is also formed of PVC, extends into the inner space 13 of the bag body 10, and is fixed to the PVC sheet 11 by fusion. The tubular body 17a is open at both ends. The lower open end of the tubular body 17a positioned outside the inner space 13 is hermetically closed by a rubber stopper 18. It should be noted that a sealing membrane member 19 formed of PVC is disposed inside the tubular body 17a and slightly above the lower end of the tubular body 17a. The present invention is directed to the nozzle member 17 comprising the sealing membrane member 19 and the tubular body 17a.

Fig. 3 is a cross sectional view showing the tubular body 17a, the sealing membrane member 19 and the rubber stopper 18 under the dismantled state. As seen from the drawing, the tubular body 17a and the sealing membrane member 19 are prepared as separate members. After injection of a peritoneal dialysing fluid from the tubular body 17a into the inner space 13 of the bag, the sealing membrane member 19 and the rubber stopper 18 are mounted to the tubular body 17a. Then, the bag 10 is sterilized within an autoclave. In this sterilizing step, the sealing membrane member 19 is thermally fused to the tubular body 17a so as to form an integral body. The dialysing fluid housed in the bag 10 is completely shielded from the outside until immediately before use of the dialysing fluid housed in the bag so as to maintain its sterility.

The peritoneal dialysis using the peritoneal dialysing fluid bag described above is carried out as follows. In the first step, the needle of a syringe is pierced through the rubber stopper 18 and the sealing membrane member 19 so as to mix a medical solution such as insulin or antibiotic into the dialysing fluid. Also, the tubular body 14 is picked up from above the bag body 10 so as to take away the upper portion 14a of the tubular body 14 from the constricted portion 15. As a result, the inner space 13 is allowed to communicate with the conduit 16 via the remaining portion of the tubular body 14 so as to permit outflow of the dialysing fluid housed in the bag 10. The bag under this condition is hung on a high position. Also, a catheter connected to the distal end of the conduit 16 is retained in an abdominal cavity of the patient. It follows that the dialysing fluid within the bag 10 is gravitationally introduced into the abdominal cavity of the patient. The dialysing fluid is retained within the abdominal cavity of the patient for a predetermined period of time so as to carry out dialysis through the peritoneum. After completion of the dialysis, the bag 10 is moved to a position lower than the position of the patient so as to discharge the used dialysing fluid into the bag 10.

The problem pointed out below remains unsolved in the nozzle member 17 comprising the sealing membrane member. Specifically, the main part of the sealing membrane member 19, which works as a sealing membrane, is formed very thin so as to facilitate the needle piercing in the step of mixing a medical solution into the dialysing fluid. The sealing membrane, which is very thin, tends to bear thermal strain in the step of sterilization within an autoclave. In some cases, cracks are formed in the sealing membrane by the thermal strain, making the membrane quite incapable of performing its function.

An object of the present invention is to prevent the sealing membrane from being strained or cracked in the step of thermally sterilizing the tubular body provided with the sealing membrane.

To achieve the object, a projection is formed in the present invention in the central portion of the sealing membrane.

According to the present invention, there is provided a nozzle member provided with a sealing membrane, comprising a tubular body, and a sealing membrane formed of a synthetic resin and

formed within the tubular body for the sealing purpose, a projection being formed on at least one surface in the substantially central portion of the sealing membrane.

In the present invention, it is desirable to form a projection on each surface of the sealing membrane. The tubular body and the sealing membrane, which are formed separately, may be attached to each other to form the nozzle member of the present invention. Alternatively, an integral structure comprising the tubular body and the sealing membrane may be prepared by molding.

The projection formed in the substantially central portion of the sealing membrane permits effectively preventing the membrane from being strained or cracked in the step of thermal sterilization, or permits markedly suppressing such strain or cracks. The reason for the prominent effect produced by the presence of the projection has not yet been clarified completely. It is considered reasonable to understand that the thickness of the sealing membrane is locally increased near the projection, leading to the prominent effect of the present invention.

The present invention, which provides a nozzle member provide with a sealing membrane, produces a prominent effect that the sealing membrane can be prevented from being strained or cracked in the step of thermally sterilizing a medical parental solution bag having the nozzle member mounted therein.

This invention can be more fully understood from the following detailed description when taken in conjunction with the accompanying drawings, in which:

Fig. 1 schematically shows a peritoneal dialysing fluid bag provided with a conventional nozzle member provided with a sealing membrane;

Fig. 2 is a cross sectional view along line II-II shown in Fig. 1;

Fig. 3 is a cross sectional view showing in a dismantled state the conventional nozzle member provided with a sealing membrane, said nozzle member being used in a peritoneal dialysing fluid bag;

Fig. 4 is a cross sectional view showing a nozzle member provided with a sealing membrane according to a first embodiment of the present invention;

Fig. 5 is a cross sectional view showing the sealing membrane included in the nozzle member shown in Fig. 4; and

Fig. 6 is an oblique and cross sectional view showing a nozzle member provided with a sealing membrane according to a second embodiment of the present invention.

A nozzle member 20 provided with a sealing membrane according to a first embodiment of the present invention is shown in Fig. 4. As seen from the drawing, the nozzle member 20 comprises a tubular body 21 manufactured by injection molding of PVC. The tubular body 21 is open at both ends, and the inner diameter of the tubular body 21 is increased at the upper end portion. An upper flange 22 and a lower flange 23 are formed along the outer circumference of the tubular body 21 in the upper end portion. Also, a sealing membrane member 24 is provided in the upper end portion having a larger inner diameter of the tubular body 21.

Fig. 5 shows in a magnified fashion the sealing membrane member 24. It is seen that the member 24 comprises a sealing membrane 25 and a side wall 26. The membrane 25 is 0.7 mm thick, and conical projections 27a, 27b are formed in the central portion of the membrane 25. Also, an inward annular projection 28 is formed in the upper portion of the side wall 26. The sealing membrane member is also formed by injection molding of PVC. The side wall 26 is brought into direct contact with the inner wall surface in the upper portion of the tubular body 21 for mounting the sealing membrane member 24 in the tubular body 21.

The nozzle member 20 described above is mounted to a peritoneal dialysing fluid bag, as already described in conjunction with Fig. 1. The side wall 26 of the sealing membrane member is fused to the inner surface of the tubular body 21 in the sterilizing step carried out in an autoclave so as to form an integral structure. It has been confirmed that the sealing membrane 25 is prevented from being strained or cracked in the sterilizing step because of the presence of the projections 27a, 27b formed in the central portion of the membrane 25. It has also been confirmed that a satisfactory effect is obtained in the case where the diameter D of the sealing membrane 25 is 5 mm, the width w and the height h of the projections 27a, 27b are 1.5 mm and 0.5 mm, respectively.

Fig. 6 shows a second embodiment of the present invention. It is seen that projections 33a, 33b are formed in the substantially central portion of a sealing membrane 32 formed within a tubular body 31. In this embodiment, the tubular body 31 has a uniform inner diameter. Also, the sealing membrane 32 and the tubular body 31 are integrally formed by injection molding.

The nozzle member 30 shown in Fig. 6 can also be used in the peritoneal dialysing fluid bag shown in Fig. 1. In this case, however, it is impossible to introduce a dialysing fluid into the bag through the tubular body 31, making it necessary to form separately an inlet port for introducing the dialysin.g fluid into the bag. The nozzle member 30 is adapted for use in, for example, a blood bag. Of course, the projections 33a, 33b permit the sealing

membrane 32 from being strained or cracked in the thermal sterilization step.

Claims

1. A nozzle member provided with a sealing membrane, comprising a tubular body (21; 31), and a sealing membrane (25; 32) formed of a synthetic resin and mounted within the tubular body (21; 31) for the sealing purpose, a projection (27a or 27b; 33a or 33b) being formed on at least one surface in the substantially central portion of the sealing membrane (25; 32).

2. The nozzle member according to claim 1, characterized in that the projection (27a or 27b; 33a or 33b) is formed on each surface of the sealing membrane.

3. The nozzle member according to claim 1, characterized in that the tubular body (21) and the sealing membrane (25) are formed separately.

4. The nozzle member according to claim 1, characterized in that the tubular body (31) and the sealing membrane (32) are formed integrally.

5. The nozzle member according to claim 1, characterized in that the projection (27a or 27b; 33a or 33b) is substantially conical and sized 0.3 to 0.7 mm in height and 1 to 5 mm in width of the bottom portion.

6. A thermally sterilized medical solution container comprising a nozzle member provided with a sealing membrane, said nozzle member (20; 30) comprising a tubular body (21; 31), and a sealing membrane (25; 32) formed of a synthetic resin and mounted within the tubular body (21; 31) for the sealing purpose, a projection (27a or 27b; 33a or 33b) being formed on at least one surface in the central portion of the sealing membrane (25; 32).

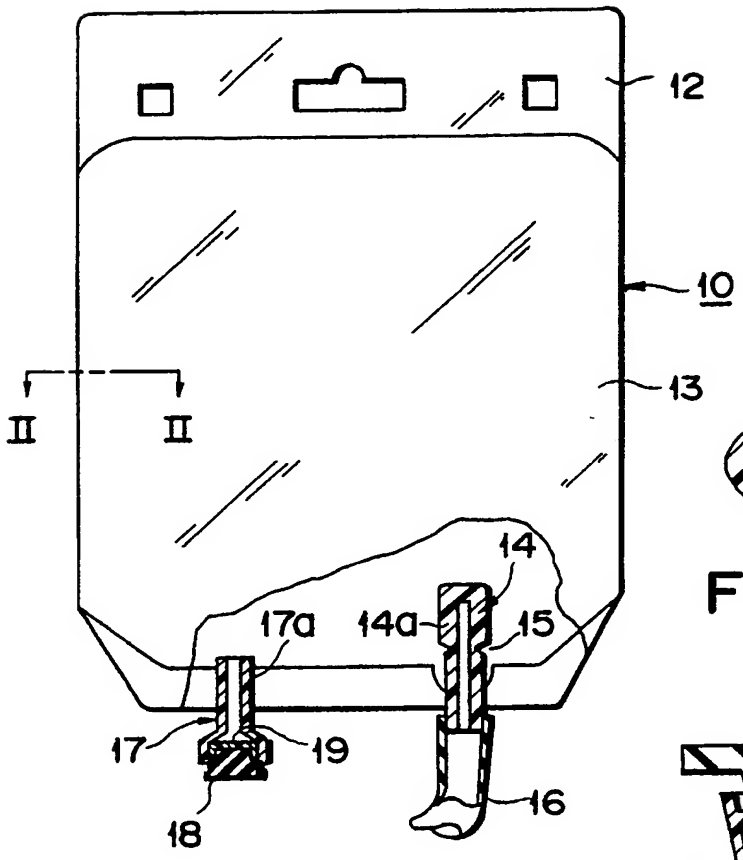

FIG. 1

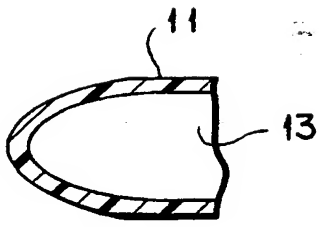

FIG. 2

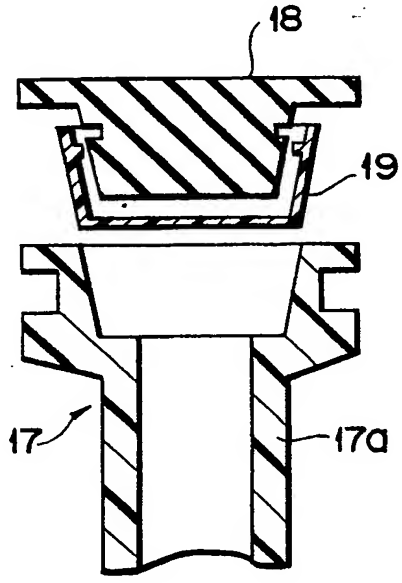

FIG. 3

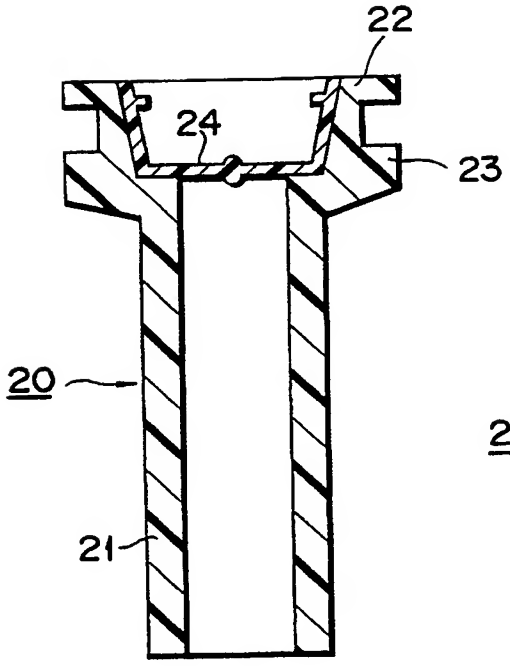

FIG. 4

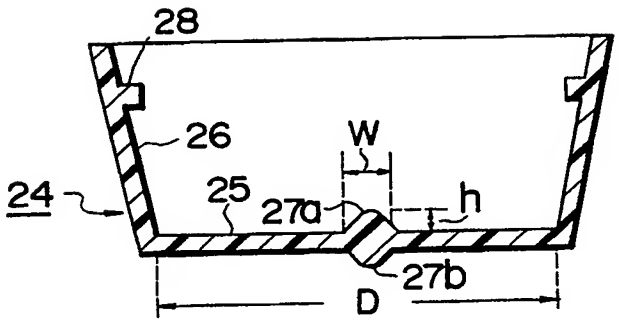

FIG. 5

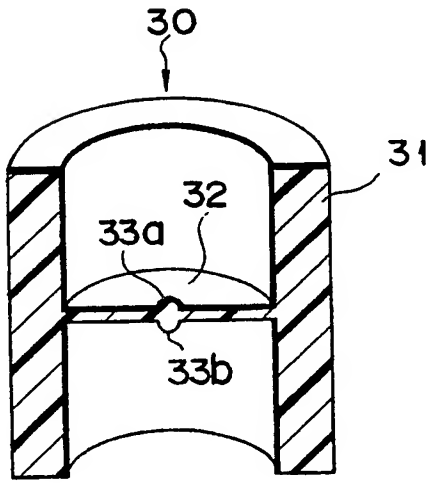

FIG. 6